REMARKS

By this Amendment, claim 10 is amended. Claims 11-18 remain in the application and stand rejected. Thus, claims 10-18 are active in the application. Reexamination and reconsideration of the application are respectfully requested.

A marked-up version of a substitute specification was submitted on July 30, 2003. In accordance with 37 C.F.R. § 1.125, attached hereto is a clean version of a substitute specification submitted on July 30, 2003. No new matter has been added. The Applicants respectfully request the Examiner to make the clean version of the substitute specification a permanent part of the application file.

In item 4 on page 2 of the Office Action, claims 10, 12, 14-15 and 18 were rejected under 35 U.S.C. § 102(e) as being anticipated by Engleson et al. (U.S. 5,781,442). Claim 10 has been amended to clarify the features of the present invention which are clearly distinguishable over the applied references.

The present invention provides an apparatus for supporting injection mixing work that is to be conducted before dosing a plurality of injections to a patient. As is described in lines 8-11 on page 1 of the original specification and in paragraph [0002] of the substitute specification, a plurality of injections are commonly dosed to a patient in a medical facility. In order to ensure that the patients do not receive injections that are incompatible with each other or which may become incompatible with each other when given to a particular patient, the apparatus of the present invention supports injection mixing work before a plurality of injections are dosed to a patient by determining a mixing order of the injections.

Claim 10, as amended, recites an apparatus for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient. The apparatus of claim 10 comprises a memory which is operable to store data for supporting injection mixing work. The memory is operable to store a patient predictability data file for storing patient predictability data, an injection prescription data file for storing injection prescription data corresponding to the patient predictability data, and a combination related data file for storing combination related data corresponding to each injection of the injection prescription data and used for determining an incompatibility for a mixing

order when each injection of the injection prescription data is combined with another injection. The apparatus of new claim 10 further comprises a display operable to display the data stored in the memory, and a controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data and to display the mixing order on the display.

Engleson et al. discloses a care management system 30 in which the management of the administration of care for patients is automated between a plurality of stations in a medical facility and/or a pharmacy. The care management system 30 is disclosed as allowing medical professionals such as nurses to monitor and regulate, in real-time, the administrations for patients. However, the care management system 30 is merely limited to monitoring or verifying "that medication is administered to the right patient, in the right dose, along the right route, and at the right time" where such monitoring is performed by the network of the care management system 30 (see column 8, lines11-13). In other words, the care management system 30 is merely a real-time verification that a patient receives the proper medications and/or treatment that were prescribed according to a physician's specific directions.

In order to ensure that patients are cared for according to a physician's orders, the care management system 30 includes a medical administration management module 110, which the Examiner is apparently considering to correspond to the controller of the present invention. The medical administration management module 110 is capable of integrating medical order information, infusion pump monitoring and bar code technology so as to support the real-time verification and charting of medications being administered to a patient (see column 6, lines 54-58). In addition, the medical administration management module 110 is disclosed as creating and maintaining an online, real-time, patient-specific medication administration record (MAR) or an integrated medication administration record (IMAR) for each patient. In other words, the medical administration management module 110 is capable of storing and gathering all of the information generated for the proper care of a patient and disseminating such information over the network (see column 6, lines 58-65). For instance, the medical administration management module 110 is disclosed as recording the start time, duration and end time of an infusion to a patient (see column 8, lines 14-29), maintaining

an online, real-time graphical medical administration record of each patient that includes past, present and future medications (see column 8, lines 30-38), and allowing nurses to perform online queries of a patient's MARs in order to assist the nurse to plan medication administration and to schedule the work load of dispensing the medication to a number of patients for which a nursing unit is responsible (see column 8, line 66 to column 9, line 16). Accordingly the care management system 30 of Engleson et al., together with the medical administration management module 110, is merely a system for ensuring that the proper medicine is delivered to the proper patient after the medicine is prescribed by a doctor and obtained from a pharmacy or hospital medicine storeroom. In other words, the care management system 30 of Engleson et al. is merely an integrated network system that assists nurses in ensuring that each patient receives the medicinal care that was prescribed by monitoring and checking the patient care for each patient in real-time.

Despite the Examiner's assertion to the contrary, Engleson et al. does not disclose or suggest an apparatus for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient, because Engleson et al. does not disclose or suggest a memory which is operable to store combination related data corresponding to each injection of the injection prescription data and used for determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection, as recited in claim 10. The care management system 30 of Engleson et al. is merely disclosed as displaying each prescription that is prescribed for a patient, and the care management system 30 operates as a real-time check list for nurses to ensure that each patient is receiving his or her prescribed care. However, Engleson et al. does not even contemplate a memory which stores combination related data which corresponds to each injection of the prescription data and which is used for determining an incompatibility or a mixing order when each injection of the prescription data is combined with another injection, as recited in claim 10. Accordingly, Engleson et al. clearly does not disclose or suggest the memory of claim 10 since Engleson et al. clearly does not disclose or suggest storing the combination related data as recited in claim 10.

Furthermore, despite the Examiner's assertion to the contrary, Engleson et al. does not disclose or suggest a controller which is operable to determine, before the injections are dosed to a

patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, as recited in claim 10.

The Examiner has again insisted, in item 5 on pages 2-3 of the Office Action and in item 18 on page 6 of the Office Action, that Engleson et al. discloses a controller which determines a mixing order for various patients. To support this conclusion, the Examiner refers to column 8, line 66 to column 9, line 12 and to figures 9 and 10 of Engleson et al. The Applicants respectfully disagree with this interpretation of Engleson et al. by the Examiner. In particular, Engleson et al. discloses that the medical administration module 110 "assists" the nurse or other health care professional to efficiently deliver care to the patients by providing the nurse the ability to perform online queries of the patients MARs and by producing reports that are designed to "assist the nurse in planning medication administration and in scheduling the workload of dispensing the medication to the many patients for which a nursing unit is typically responsible" (see column 8, lines 66 to column 9, line 6). In other words, with reference to figure 9 of Engleson et al., the medical administration management module 110 merely provides a visual display of a patient's IMAR which indicates all of the medications that were prescribed for a patient, the times that the medications are to be given, and the amounts of each medications so as to "assist" the nurse in ensuring that each medication is given on the prescribed time and for the prescribed amounts. The IMAR of figure 9 is pre-generated and merely contains each of the medications that were prescribed for a particular patient, and the task list of figure 10 is merely a schedule of drug administration for a number of patients which "assists" the nurse to plan accordingly so as to "ensure that all medication is given promptly" (see column 9, lines 6-16). Accordingly, the medical administration management module 110 merely generates a visual display of a patient's MAR or IMAR to illustrate each of the prescribed medications, the times the medications are to be given, and the amounts of each medication for the patient.

The medical administration management module 110, however, does not determine a mixing order of the injections since the medical administration management module 110 merely allows the care management system 30 to monitor whether a proper administration or dosing of a prescription has been conducted and since the medications that are visually displayed on the display screen are not determined by the medical administration management module 110 but are merely a reflection of

either the order in which the medications are entered into the system or the order in which a physician prescribed the medications.

Accordingly, Engleson et al. clearly does not disclose or suggest a controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, as recited in claim 10.

Therefore, the Applicants respectfully submit that Engleson et al. clearly does not anticipate claim 10 since Engleson et al. does not disclose or suggest each and every limitation of claim10.

In item 11 on page 4 of the Office Action, claims 11 and 16 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engleson et al. in view of Merki et al. (U.S. 5,002,055). In addition, in item 14 on page 5 of the Office Action, claims 13 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Engleson et al. in view of Mayaud (U.S. 5,845,255). For the following reasons, the Applicants respectfully submit that Merki et al. and Mayaud, either individually or in combination, do not cure the deficiencies of Engleson et al. for failing to disclose or suggest each and every limitation of clam 10.

In item 19 on page 7 of the Office Action, the Examiner noted that claim 10, as added in the July 30, 2003 Amendment, did not recite a combination data file corresponding to how a plurality of injections will react when combined with one another. As described above, claim 10 was amended to define the combination related data as corresponding to each injection of the injection prescription data and as being used for determining an incompatibility or a mixing order when each injection of the injection prescription data is combined with another injection.

In items 15 and 16 on pages 5-6 of the Office Action and in item 19 on page 7 of the Office Action, the Examiner asserts that Mayaud discloses storing incompatibility data showing whether or not a combination of two kinds of injections is incompatible.

Mayaud discloses reviewing for contraindications of drugs and for special precautions, such as a patient's allergies, for a drug's use. However, Mayaud merely discloses a prescription management system for avoiding possible drug-to-drug interactions with other drugs that have been previously prescribed. (see column 31, lines 19-24 and 33-39). That is, Mayaud merely discloses a

screening or reviewing system for avoiding possible unintended adverse outcomes between a previously prescribed medication and a possible new medication that is to be prescribed to a patient. That is, Mayaud merely discloses a screening process for avoiding possible adverse outcomes between previously prescribed medications and a possible new medication. Mayaud, however, does not disclose or suggest an apparatus for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient having a memory which is operable to store combination related data which corresponds to each injection of the injection prescription and which is used for determining an incompatibility or a mixing order when each injection of the injection data is combined with another injection, as recited in claim 10.

Furthermore, Mayaud does not disclose or suggest a controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, as recited in claim 10. Accordingly, Mayaud clearly does not cure the deficiencies of Engleson et al. for failing to disclose or suggest the memory which is operable to store the combination related data as defined in claim 10 and the controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, as recited in claim 10.

The Applicants note that the Examiner, in item 19 on page 7 of the Office Action, asserted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. However, the Examiner is reminded that an obvious combination of references cannot result in disclosing each and every limitation of a claim when none of the references, either individually or in combination, disclose or suggest each and every limitation of the claim. Therefore, since neither Engleson et al. nor Mayaud disclose or suggest, either individually or in combination, the memory which is operable to store the combination related data as defined in claim 10 or the controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, the Applicants respectfully submit that claim 10 is clearly patentable over the combination of Engleson et al. and Mayaud.

Furthermore, the Applicants respectfully submit that Merki et al. does not cure the deficiencies of Engleson et al. and Mayaud for failing to disclose or suggest each and every limitation of claim 10. In particular, Merki et al. discloses a gastric pH sensor 1 for intraluminally measuring the H^+-ion activity of gastric juices. Merki et al. also discloses that the measured pH data resulting from the infusion of a primary medication are stored and compared with the reference values that are stored in a microprocessor. Merki et al. discloses that, during the infusion of a prescribed medication, another medication can be combined with the prescribed medication when the measured pH values are deemed to be unacceptable so as to achieve the desired therapy objective. However, combining the primary medication with another medication is only performed when the measured pH values indicate a deviation of the therapy objective after dosing of the primary medication is performed, which is clearly unrelated to supporting injection mixing work that is to be conducted before dosing a plurality of injections to a patient, as recited in claim 10. Accordingly, the Applicants respectfully submit that Merki et al. clearly does not cure the deficiencies of Engleson et al. and Mayaud for failing to disclose or suggest an apparatus for supporting injection mixing work to be conducted before dosing a plurality of injections to a patient since Merki et al. does not disclose or suggest a memory which is operable to store the combination related data which correspond to each injection of the injection prescription data and which is used for determining an incompatibility or a mixing order when each injection of the injection mixing data is combined with another injection, and a controller which is operable to determine, before the injections are dosed to a patient, a mixing order of the injections contained in the injection prescription data in accordance with the combination related data, as recited in claim 10.

Accordingly, the Applicants respectfully submit that claim 10 is clearly patentable over the combination of Engleson et al, Merki et al. and Mayaud since Engleson et al., Merki et al. and Mayaud, either individually or in combination, fail to disclose or suggest each and every limitation of claim 10. Accordingly, since Engleson et al., Merki et al. and Mayaud fail to disclose or suggest each and every limitation of claim 10, no obvious combination of Engleson et al., Merki et al. and Mayaud would result in the invention of claim 10.

Because of the clear distinctions discussed above, the Applicants respectfully submit that the collective teachings of Engleson et al., Merki et al. and Mayaud do not meet each and every limitation of claim 10. Moreover, the Applicants respectfully submit that it would not have been obvious to a person having ordinary skill in the art to modify Engleson et al., Merki et al. and Mayaud or to make any combination of the references of record in such a manner as to result in, or otherwise render obvious, the present invention as recited in claim 10. Therefore, it is respectfully submitted that claim 10, as well as claims 11-18 which depend therefrom, are clearly allowable over the prior art of record.

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is clearly in condition for allowance. An early notice thereof is respectfully solicited.

If, after reviewing this Amendment, the Examiner feels there are any issues remaining which must be resolved before the application can be passed to issue, it is respectfully requested that the Examiner contact the undersigned by telephone in order to resolve such issues.

A fee and a Petition for a two-month Extension of Time are filed herewith pursuant to 37 CFR § 1.136(a).

Respectfully submitted,

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